



0602 '98 SEP 18 A9:45

September 14, 1998

Food and Drug Administration
Dockets Management Branch
FDA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Madam:

The attached letter was sent to you via e-mail on September 11, 1998 with the promise of a hard copy to follow. Please date stamp and return one of the additional enclosed copies for our records.

Thank you.

Sincerely,

Stacey Robertson, Program Associate
Technology & Regulatory Affairs

98N-0339

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September 11, 1998

Food and Drug Administration
Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**RE: Docket 98-N0339, Comments on Implementation of FDAMA
Center for Biologics Evaluation and Research**

Dear Sir:

The Health Industry Manufacturers Association (HIMA) appreciates this opportunity to submit these comments on how the Center for Biologics Evaluation and Research can implement the FDA Modernization Act and meet its statutory obligations under the Food, Drug and Cosmetic Act. HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. CBER's regulation of devices is an import issue for many of our members.

1. *Are there objectives or issues related to the Agency's statutory obligations other than the six objectives identified in FDAMA?*

FDAMA covers the broad range of agency activities. From the medical device industry perspective, focusing on reducing the current product review backlog will be more than enough to keep CBER busy for quite some time. If FDA accomplishes all the objectives outlined by FDAMA in the timeframes specified by Congress, we in industry will be more than willing to look at ways to tweak the system to gain even greater efficiencies.

The one thing we might add is a reminder that FDA's mission has been broadened. The focus is not only the protection of the public health but also promotion of the public health. This change in focus results in a delicate balancing of the risks and benefits in an environment that is essentially risk adverse. We hope that FDA will develop a reasonable approach to its revised mission that will direct future agency activities.

2. *What should FDA do to adequately meet the demands that are beginning to pressure the application review process?*

CBER has made significant strides toward improving its licensure processes. Replacement of the PLA and ELA with the blood license application process shows great promise. We believe that improvements like this will make the licensure process more

efficient and look forward to the same efforts being made to improve CBER's review and regulation of medical devices.

CBER's focus on products covered by the Prescription Drug User Fee Act (PDUFA) and blood and plasma establishments has left the medical device industry at the end of the line in terms of product reviews. As a result, some products have been under review for more than 18 months and few others for 24 months. Many of the products are me-too products. CBER reviewers have often remarked to complaining manufacturers that their products are not covered by user fees and they must wait until the PDUFA products are reviewed. Such statements have caused the medical device industry much consternation.

We suggest the following:

- ✓ CBER should consider reallocating some of its resources to clear up the backlog of device reviews much like its sister Center, CDRH. Consider allowing research staff to conduct product reviews to reduce the backlog of product reviews.
 - ✓ To reduce the workload, harmonize device review processes (instrumentation) with CDRH review processes so that devices that can be used for blood screening or diagnosis will not require a dual review. Allow CDRH to take the lead and where necessary to address specific CBER concerns, add review requirements.
 - ✓ Reevaluate the necessity for the current lot release requirements.
 - ✓ Make available more templates to make the submission and review processes simpler.
 - ✓ Evaluate current processes to determine what things add no or little value to the process. Stop all functions with no or little pay-off.
 - ✓ Publish flow charts or internal processes for all submissions so that the process is transparent.
 - ✓ Hold the leadership in review division accountable for the performance of their staff.
 - ✓ Allow third-party review organizations to review submissions.
 - ✓ Implement section 119 of FDAMA to make the review process more predictable.
 - ✓ Finally, remember that part of promotion of the public health is getting good products to the market.
3. *How can FDA work with its partners to ensure that products produced and marketed by regulated industry are high quality and provide consumer protection?*

Product quality is important to both CBER and industry. The fact that quality is a joint concern is often overlooked. Manufacturers have both a moral and legal responsibility to ensure that their products are of the highest quality possible. Their goal is to design in quality.

We believe that CBER has at its disposal an arsenal of tools to help ensure product quality. These tools include the opportunity for early and frequent meetings with industry to help design study protocols, good technical reviews and an efficient and effective compliance program. Application of the device quality systems regulations, particularly the design control provisions, to devices regulated by CBER is another important tool. CBER, to its credit has always been willing to meet with industry to discuss clinical protocols and the content of product submissions.

In light of the design control requirements, CBER should reevaluate the current requirements for lot release. This program implies that manufacturers can test in quality. Efficiencies in this process may also be gained by reviewing the programs used by other countries.

4. *How can FDA best establish and sustain effective, timely and review-based postmarketing surveillance systems for reporting injuries associated with all FDA regulated products?*

To improve the timeliness of the process, FDA should establish an electronic metrics-based quality system for capturing, analyzing and reporting postmarket surveillance data. FDA also should review and assess mechanisms used by other agencies, industries and countries to obtain similar data.

5. *What approach should FDA use to ensure that it has continued access to the scientific expertise needed to meet its statutory obligations and strengthen its science based decision process?*

CBER should make more use of scientific workshops to gain a broader perspective on scientific and technical issues. The current advisory committee is often perceived as a rubber stamp for CBER activities. Workshops permit an open dialogue and exchange of ideas, which is precluded by the advisory committee structure. CBER has already conducted a workshop addressing implementation of nucleic acid testing for HIV-1 for blood screening and another is planned for nucleic for hepatitis and other viruses.

We realize that workshops can be resource intensive. FDA should consider allowing industry or professional associations to sponsor the workshops where possible.

The "vendor day" program should be expanded to include products regulated by CBER. In addition, CBER reviewers should be allowed to make site visits to companies to gain a better understanding of the products regulated by CBER.

6. *How can FDA best maximize its outreach efforts to ensure the availability and clarity of information about new products and about the process for review of applications and submissions related to the Agency's statutory regulations?*

CBER's outreach programs for the blood community are important and should be continued. Use of the website, fax-on-demand, and public meetings should continue to be used to convey information. Interactions with professional organizations provide another opportunity to provide important information to the public.

With regard to providing information about new products, new product promotion is not a FDA function. Notification of product approvals via the *Federal Register* or the CBER website is sufficient to provide the public notice regarding new product availability.

On certain levels, CBER's communications with the medical device industry have improved. CBER has published a number of guidance documents and has given industry an opportunity to comment. However, more is needed.

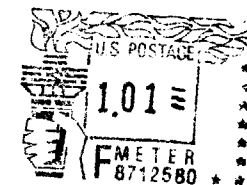
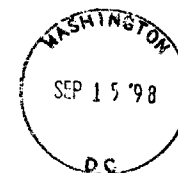
The medical device industry should be given the opportunity for meaningful participation in the guidance development process. CDRH has already recognized that much can be gained from early interaction between the agency and industry during the guidance development process. In fact, industry has developed the strawman for a number of guidance documents. We believe that CBER guidances could benefit from this type of collaborative effort as well.

If you have any questions regarding these comments, please feel free to contact me.

Sincerely,



Carolyn Jones
Director, Technology and Regulatory Affairs



FIRST CLASS

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